

What are the benefits of participating in this research study?

If your baby has a metabolic disorder that is not in the mandated newborn screening testing, the disorder may be identified by this research study. Early identification and treatment of metabolic disorders could prevent physical and mental disabilities, and in some cases, even death.

By participating in the study, you are also helping the Hawai'i Newborn Metabolic Screening Program decide which disorders to add to mandated newborn screening in the future. This will benefit future newborns with these disorders.

What are the risks of participating in the research study?

Your baby will experience no additional discomfort beyond the heel stick normally done for mandated newborn screening.

For some babies, the supplemental screening results will indicate that further diagnostic testing is necessary. In most cases, the additional diagnostic testing will show that the baby does not have a disorder.

Will there be any compensation for participating in the research study?

There will not be any compensation to participate in this research study. If a disorder is diagnosed, the cost of the treatment is not paid for by this research project.

What if I have more questions?

For any questions on this research project, you may contact Christine Matsumoto, R.N.,M.P.H., Newborn Metabolic Screening Program Coordinator at (808) 733-9069.

The Department of Health provides access to its activities and programs without regard to race, color, national origin (including language), age, sex, religion, or disability. Write our departmental Affirmative Action Officer at Box 3378, Honolulu, HI 96801-3378, or call this program at (808) 586-4616 (voice TTY) within 180 days of a problem.

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MORE INFORMATION ABOUT SUPPLEMENTAL NEWBORN SCREENING



*Newborn
Metabolic
Screening
Program*

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Supplemental Tests For Your Baby

You are being asked to participate in a research project to evaluate additional newborn screening tests for metabolic disorders. This supplemental testing will use the same blood specimen that has already been drawn for the mandated newborn screening testing. No additional blood from your baby will be needed, and there is no additional cost to you. In the hospital, you will be asked to sign a form to let the testing laboratory staff know whether or not you want your baby to participate in this research project.

Participation in this research study is voluntary, and if you decide not to participate at any time, you will not lose any existing benefits or services. Your baby will still receive mandated newborn screening testing.

What are metabolic disorders?

Metabolic disorders affect the body's ability to produce or break down compounds such as proteins, fats, or carbohydrates into smaller substances needed by the body for energy, growth and repair. Too much of certain substances and/or too little of others can cause major health problems. If identified early, some of these disorders can be treated before they cause serious health problems. Treatment may include close monitoring of the person's health, medication, dietary supplements, and/or special diets.

Will I find out about my baby's results?

Only samples unsuitable for testing and unusual results will be reported to your baby's doctor, who will discuss this with you. A "positive" or "unusual" test result will be reported when a disorder is suspected and/or additional testing is needed. Reporting of the positive or unusual results of supplemental testing may be delayed due to the mandated newborn screening testing being done first. If the specimen is unsuitable for supplemental testing, the research testing will not be done.

What happens if the results are positive or unusual?

Your baby's doctor will be contacted if there are any positive or unusual test results. Further testing will be needed to find out if your newborn has a disorder. Your baby will be referred to a doctor who specializes in the treatment of metabolic disorders. The specialist will examine the baby and possibly order more tests. These confirmatory tests will be paid for by the Hawai'i Newborn Metabolic Screening Program.

If your baby is found to have a disorder, the specialist will assist you and your baby's doctor in treating your baby's special health care needs.

It is important to remember that a positive or unusual result does not always mean that a disorder is present. **This is only a screening test that may tell the doctor to do more testing to determine if your baby has a disorder.**

A Screening test only finds those babies who may be at risk for a disorder. Only additional testing (diagnostic testing) can tell us if the baby really has the disorder.

There could also be disorders identified by the study which may not cause significant health problems or require treatment. There may also be disorders identified for which there is no effective treatment. There is also a chance that these rare disorders could be missed by this test since it is only a screening test.

What if someone in my family has a metabolic disorder or I want private testing?

Discuss this with your doctor and let your doctor know if there is family history of a metabolic disorder, or a special concern.

Supplemental testing outside of, or **in addition to, the research study** may be obtained through private commercial laboratories. Optional supplemental screening is offered for a fee by Baylor University Medical Center (Dallas, Texas www.baylor-dallas.edu/newbornscreening/) or NeoGen Screening Inc. (Bridgeville, Pennsylvania www.neogenscreening.com).